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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, STATES OF CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, AND WASHINGTON; THE COMMONWEALTHS OF MASSACHUSETTS AND VIRGINIA; and THE DISTRICT OF COLUMBIA, *ex rel.* ZACHARY SILBERSHER, Plaintiffs, vs. JANSSEN BIOTECH, INC., JANSSEN ONCOLOGY, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, JOHNSON & JOHNSON, and BTG INTERNATIONAL Defendants.	Civil Action No. 19-12107 (KM) (ESK) **DEFENDANTS' JOINT REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF DEFENDANTS' JOINT MOTION TO DISMISS SECOND AMENDED COMPLAINT** *Document electronically filed*

Defendants Janssen Biotech, Inc., Janssen Oncology, Inc., Janssen Research & Development, LLC, Johnson & Johnson ("J&J Defendants"), and BTG International Limited ("BTG") (collectively, "Defendants"), pursuant to Federal Rule of Evidence 201, respectfully request that this Court take judicial notice of the following documents, true and correct copies, excerpted in accordance with Local Civ. RULE 5.2(8) and highlighted for the Court's ready identification, of which are attached:[1]

Exhibit A – U.S. Patent No. 5,604,213 (issued Feb. 18, 1997).

Exhibit B – U.S. Patent No. 8,822,438 (issued Sept. 2, 2014).

Exhibit C – Applicant Arguments, Notice of Appeal, and Other Reference-Appeal Documents, submitted June 4, 2013, for U.S. Patent Application No. 13/034,430 (filed Feb. 24, 2011), *available at* https://portal.uspto.gov/pair/PublicPair.

Exhibit D – Petition, *Amerigen Pharm., Ltd. v. Janssen Oncology, Inc.*, IPR2016-00286 (P.T.A.B. Dec. 4, 2015), *available at* https://ptab.uspto.gov/#/login.

Exhibit E – Petition, *Mylan Pharm., Inc. v. Janssen Oncology, Inc.*, IPR2016-01332 (P.T.A.B. June 30, 2016), *available at* https://ptab.uspto.gov/#/login.

Exhibit F – Petition, *Wockhardt Bio AG v. Janssen Oncology, Inc.*, IPR2016-01582 (P.T.A.B. Aug. 10, 2016), *available at* https://ptab.uspto.gov/#/login.

Exhibit G – Michael S. Cookson et. al, *Castration-Resistant Prostate Cancer: AUA Guideline*, AMERICAN UROLOGY ASSOCIATION EDUCATION AND RESEARCH, INC. (2013).

Exhibit H – GSA Drugs, Pharmaceuticals & Hematology Related Products Solicitation, 01 – Solicitation Document, Standing Solicitation No. M5-Q50A-03-R8.

[1] For the Court's convenience, Exhibits A through RR are included as part of a hyperlinked Appendix A submitted under separate cover in support of Defendants' Joint Motion to Dismiss.

Exhibit I – Specification, submitted Feb. 24, 2011, for U.S. Patent Application No. 13/034,430 (filed Feb. 24, 2011), *available at* https://portal.uspto.gov/pair/PublicPair.

Exhibit J – Excerpt from Certified File Wrapper of U.S. Patent No. 8,822,438, Patent Application No. 13/034,340 (filed Feb. 24, 2011).

Exhibit K – Johnson & Johnson, Form 10-Q (Nov. 4, 2016).

Exhibit L – Johnson & Johnson, Form 10-Q (Aug. 4, 2016).

Exhibit M – Johnson & Johnson, Form 10-Q (May 9, 2016).

Exhibit N – Johnson & Johnson, Form 10-K (Feb. 24, 2016).

Exhibit O – Elaine A. Mostaghel, *Abiraterone in the Treatment of Metastatic Castration-Resistant Prostate Cancer*, CANCER MANAGEMENT RESEARCH (2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3912049/.

Exhibit P – *Patent Board Grants Inter Partes Review of Cancer-Fighting Therapy*, 24-1 MEALEY'S(R) LITIG. REP.: PATENTS 12 (2016).

Exhibit Q – Dr. Cary Millner & Kunyong Yang, *United States: PTAB Institutes Separate IPR Proceedings Filed By Codefendants, Finding That The Later IPR Proceeding Was Not Barred by 35 U.S.C. § 325(d), PTAB Litigation Blog*, MONDAQ BUS. BRIEFING (Feb. 7, 2017).

Exhibit R – *Zytiga To Face Challenges*, BUSINESS MONITOR ONLINE (Nov. 3, 2016).

Exhibit S – Jan Berger et al., *How Drug Life-Cycle Management Patent Strategies May Impact Formulary Management*, 22 (16 supp.) AJMC (Jan. 20, 2017), https://www.ajmc.com/journals/supplement/2016/how-drug-life-cycle-management-patent-strategies-may-impact-formulary-management/a636-article.

Exhibit T – Silas Inman, *FDA Approves Pre-Chemo Enzalutamide for mCRPC*, ONCLIVE (Sept. 10, 2014), https://www.onclive.com/web-exclusives/fda-approves-pre-chemo-enzalutamide-for-mcrpc.

Exhibit U – Donald L. Trump, *FDA Approves Enzalutamide for Metastatic Castration-Resistant Prostate Cancer*, HEMONC TODAY (Sept. 25, 2012), https://www.healio.com/hematology-oncology/prostate-cancer/news/print/hemonc-today/%7B9c47a439-aef9-4380-bdce-0e6843a2d524%7D/fda-approves-enzalutamide-for-metastatic-castration-resistant-prostate-cancer.

Exhibit V – Amit Bahl et al., *Second-Line Treatment Options in Metastatic Castration-Resistant Prostate Cancer: A Comparison of Key Trials with Recently Approved Agents*, CANCER TREATMENT REVIEWS (Aug. 16, 2013), https://doi.org/10.1016/j.ctrv.2013.06.008.

Exhibit W – H. Lee Mofflitt Cancer Ctr. & Res. Inst., *Researchers Identify Inhibitor that Overcomes Drug Resistance in Prostate Cancer*, SCIENCEDAILY (June 12, 2017), www.sciencedaily.com/releases/2017/06/170612124417.htm.

Exhibit X – Emmanuel S. Antonakaris, *Current Understanding of Resistance to Abiraterone and Enzalutamide in Advanced Prostate Cancer*, CLINICAL ADVANCES IN HEMATOLOGY & ONCOLOGY (May 2016), http://www.hematologyandoncology.net/archives/may-2016/current-understanding-of-resistance-to-abiraterone-and-enzalutamide-in-advanced-prostate-cancer/.

Exhibit Y – Andrew Pollack, *New Drug For Prostate Cancer Gets F.D.A. Nod*, N.Y. TIMES (Aug. 31, 2012), https://www.nytimes.com/2012/09/01/business/fda-approves-prostate-cancer-drug.html.

Exhibit Z – Naoki Terada et al., *Exploring the Optimal Sequence of Abiraterone and Enzalutamide in Patients with Chemotherapy-Naïve Castration-Resistant Prostate Cancer: The Kyoto-Baltimore Collaboration*, 24 INT'L J. OF UROLOGY (Apr. 28, 2017), https://doi.org/10.1111/iju.13346.

Exhibit AA – Dennis Thompson, *Early Chemo May Boost Survival in Advanced Prostate Cancer*, WEBMD (May 14, 2015), https://www.webmd.com/prostate-cancer/news/20150514/early-chemo-may-boost-survival-in-advanced-prostate-cancer#1.

Exhibit BB – Todd Campbell, *Can Xtandi Become the Go-To Prostate Drug?*, AOL FINANCE (Sept. 20, 2013), https://www.aol.com/article/finance/2013/09/20/can-xtandi-become-the-go-to-prostate-drug/20725994/#.

Exhibit CC – Andrew Pollack, *New Drugs Fight Prostate Cancer, but at High Cost*, N.Y. TIMES (June 27, 2011), https://www.nytimes.com/2011/06/28/health/28prostate.html.

Exhibit DD – *What Is ZYTIGA® (Abiraterone Acetate)?*, ZYTIGA® (archived October 15, 2017), https://web.archive.org/web/20171015195728/https:/www.zytiga.com/.

Exhibit EE – *How should I take XTANDI?*, XTANDI® (archived October 6, 2017), https://web.archive.org/web/20171006005848/https:/www.xtandi.com/.

Exhibit FF – *Why make JEVTANA your next step?*, JEVTANA® (archived October 5, 2017), https://web.archive.org/web/20171005083102/http:/www.learnaboutjevtana.com/.

Exhibit GG – Dep't of Veterans Affairs, National Acquisition Center (CCST), Item Details: 57894-0150-12, https://www.vendorportal.ecms.va.gov/NAC/Pharma/Details?NDC=57894019506&CNT=36F79719D0217 (last visited Feb. 20, 2019).

Exhibit HH – U.S. Dep't of Veterans Affairs, National Acquisition Center (CCST), Item Details: 57894-0195-06; https://www.vendorportal.ecms.va.gov/NAC/Pharma/Details?NDC=57894015012&CNT=36F79719D0217 (last visited Feb. 20, 2019).

Exhibit II – Maxx Chatsko, *Can Zytiga Build on a Historic 2012?*, THE MOTLEY FOOL (Feb. 19, 2013), https://www.fool.com/investing/general/2013/02/19/can-zytiga-build-on-historic.aspx.

Exhibit JJ – Jillian Dabney, *Analyzing Medivation's Growth Opportunity with Xtandi,* YAHOO! FINANCE (May 12, 2016), https://finance.yahoo.com/news/analyzing-medivation-growth-opportunity-xtandi-133503575.html.

Exhibit KK – Charles J. Ryan, *mCRPC Treatment: The Right Treatment for the Right Patient at the Right Time: Everyday Urology*, EUROTODAY (June 2016), https://www.urotoday.com/images/journal_issues/everyday-urology-volume-1-issue-4.pdf.

Exhibit LL – Da Hee Han, *New Zytiga Tablet Strength Availability*, MPR (May 17, 2017), https://www.empr.com/home/news/new-zytiga-tablet-strength-available/.

Exhibit MM – Christian Nordqvist, *Xtandi (Enzalutamide) Approved For Late Stage Prostate Cancer, FDA*, MEDICALNEWSTODAY (Sept. 3, 2012), https://www.medicalnewstoday.com/articles/249785.php.

Exhibit NN – *Natco Pharma files new drug applications with USFDA*, LIVEMINT (Feb. 10, 2015), https://www.livemint.com/Companies/PMLycu8RnqNhVacGWcYjaP/Natco-Pharma-files-new-drug-applications-with-USFDA.html.

Exhibit OO – U.S. Patent Application No. 13/034,340, Publication No. US-2011-0144016-A1 (Published date June 6, 2011) (Alan H. Auerbach, applicant).

Exhibit PP – *Xtandi, Drugs@FDA: FDA Approved Drug Products*, FDA (archived May 15, 2017), https://web.archive.org/web/20170515143313/https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=203415.

Exhibit QQ – *NDA Approval Letter*, DEPT. OF HEALTH AND HUMAN SERVS. (archived Feb. 18, 2017), https://web.archive.org/web/20170218015522/http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/203415Orig1s000ltr.pdf.

Exhibit RR – *Summary Review, Application No. 203415Orig1s000*, CENTER FOR DRUG EVALUATION AND RESEARCH (archived Feb. 17, 2017), https://web.archive.org/web/20170217110137/http://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/203415Orig1s000SumR.pdf.

Exhibit SS – Dep't of Veterans Affairs, National Acquisition Center (CCST), Item Details: 57894-0150-12, https://www.va.gov/nac/Pharma/Details?NDC=57894015012&CNT=V797P-5230B (last visited Apr. 5, 2021).

Exhibit TT – U.S. Dep't of Veterans Affairs, National Acquisition Center (CCST), Item Details: 57894-0195-06; https://www.va.gov/nac/Pharma/Details?NDC=57894019506&CNT=V797P-5230B (last visited Apr. 5, 2021).

RELEVANT AUTHORITY

When evaluating a motion to dismiss, courts may "review documents attached to the complaint and matters of public record" in addition to the complaint itself. *Nationwide Mut. Ins. Co. v. Caris*, 170 F. Supp. 3d 740, 745 (D.N.J. 2016). Courts may also "judicially notice a fact that is not subject to reasonable dispute," because it "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b).

The attached Exhibits fall within categories of documents that courts have recognized as judicially noticeable. Courts may take judicial notice of such materials to determine whether a qualifying public disclosure occurred, without converting the motion to dismiss into one for summary judgment. *See, e.g.*, *U.S. ex rel. Hunt v. Merck-Medco Managed Care, L.L.C.*, 336 F. Supp. 2d 430, 446 n.12 (E.D. Pa. 2004); *U.S. ex rel. Spay v. CVS Caremark Corp.*, 913 F. Supp. 2d 125, 142 (E.D. Pa. 2012); *U.S. ex rel. Ambrosecchia v. Paddock Labs., LLC*, 855 F.3d 949, 954–55 (8th Cir. 2017) ("amended public disclosure bar is appropriately resolved on a motion to dismiss, even assuming that it no longer poses a jurisdictional question" and "[i]n evaluating whether the public disclosure bar applies, [courts] may consider … items subject to judicial notice.").

Exhibits A through H are judicially noticeable because they are documents relevant to "matters incorporated by reference or integral to the claim." *Buck v. Hampton Twp. Sch. Dist.*, 452 F.3d 256, 260 (3d Cir. 2006). Exhibits A and B are the two patents upon which Relator's Second Amended Complaint ("SAC") relies. Exhibit C is Defendants' June 4, 2013 patent-prosecution filing ("the June 4 Submission") submitted in Application No. 13/034,340 ("the '340 Application") and referenced in the SAC. *See* SAC ¶¶ 82, 87. The June 4 Submission is central to the SAC because the SAC alleges that the submission contained fraudulent misrepresentations

and/or omissions to the United States Patent & Trademark Office ("PTO"). Exhibits D, E, and F are *inter partes* review petitions cited by Relator in the SAC. *Id.* ¶ 101. Exhibit G is an American Urology Association guideline from 2013 on which Relator premises one of his allegations. *Id.* ¶ 87(d). Exhibit H is a General Services Administration solicitation document from which Relator quotes in support of his claims. *Id.* ¶ 114.

Exhibits I through Z and AA through FF, as well as Exhibit OO are judicially noticeable because they are "matters of public record." *Buck*, 452 F.3d at 260. Exhibits I and J are documents that were submitted by the J&J Defendants during the '438 patent prosecution and are available via the PTO's Public Patent Application Information Retrieval System ("PAIR"). Similarly, Exhibit OO is the Notice of Publication for the '340 Application and available on Public PAIR. Courts may take judicial notice of information available from PAIR. *E.g.*, *TransCardiac Therapeutics, Inc. v. Yoganathan*, 15 F. Supp. 3d 1364, 1372 n.12 (N.D. Ga. 2014); *RB Rubber Prods., Inc. v. ECORE Int'l, Inc.*, No. 3:11-cv-319-AC, 2012 WL 860416, at *5 (D. Or. Mar. 13, 2012). Exhibits K, L, M, and N are publicly filed 10-Q and 10-K disclosures. SEC filings are subject to judicial notice. *See Spay*, 913 F. Supp. 2d at 139.

Exhibits O through Z, AA through CC, and II through NN are online articles or reports that are available to the public. Defendants request these documents to be judicially noticed not for the truth of the information, but for "what was known and in existence in the public realm at the time." *Id.* at 142.

Exhibits DD through FF, and Exhibits PP through RR are screenshots of webpages from 2017, accessed via the Wayback Machine, an internet archive that reflects how a given webpage appeared at a prior point in time. "Courts have taken judicial notice of the contents of web pages available through Wayback Machine as facts that can be accurately and readily determined from

sources whose accuracy cannot reasonably be questioned." *Erickson v. Neb. Mach. Co.*, No. 15-CV-01147-JD, 2015 WL 4089849, at *1 n.1 (N.D. Cal. July 6, 2015); *see also Williams v. Ying Zhou*, No. Civ. No. 14-5544, 2019 WL 1379876, at *4 (D.N.J. Mar. 27, 2019).

Exhibits GG, HH, SS, and TT are webpages published by the Department of Veterans Affairs' website that reflect that Zytiga is offered for sale to the government on a Federal Supply Schedule. Exhibits PP through QQ are webpages published by the U.S. Food and Drug Administration on its "Drugs@FDA" database. The Court may take judicial notice of documents available from reliable sources on the internet, such as websites run by Government agencies. *See, e.g.*, *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 754 n.2 (E.D. Pa. 2003) (taking judicial notice of reports published on the FDA website).

Because all of the exhibits referenced herein are judicially noticeable, Defendants respectfully request the Court to take judicial notice of each of the attached Exhibits for purposes of showing the existence of the Exhibits, their dates of publication, and the public availability of their contents.

Dated: April 6, 2021

Respectfully submitted,

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